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| 24737 Philips inte | 7590 04/20/200 ELLECTUAL PROPER | | EXAMINER | | |
| P.O. BOX 300 | 1 | | BOR, HELENE CATHERINE | CATHERINE | |
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| | Application No. | Applicant(s) | |
| Office Action Summer | 10/541,624 | SABCZYNSKI ET AL. | |
| Office Action Summary | Examiner | Art Unit | |
| | Helene Bor | 3768 | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | correspondence addre | ss |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this comm D (35 U.S.C. § 133). | · |
| Status | | | |
| Responsive to communication(s) filed on <u>06 Jules</u> This action is FINAL . 2b)⊠ This Since this application is in condition for allower closed in accordance with the practice under E | action is non-final. | | erits is |
| Disposition of Claims | | | |
| 4) Claim(s) 1-17 is/are pending in the application. 4a) Of the above claim(s) is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) 1-17 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or Application Papers 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the ore Replacement drawing sheet(s) including the correction 11) The oath or declaration is objected to by the Examine 11) The oath or declaration is objected to by the Examine 11) The oath or declaration is objected to by the Examine 11) The oath or declaration is objected to by the Examine 11) The oath or declaration is objected to by the Examine 11) The oath or declaration is objected to by the Examine 11 the oath or declaration is objected to by the Examine 11 the oath or declaration is objected to by the Examine 12 the oath or declaration is objected to by the Examine 13 the oath or declaration is objected to by the Examine 14 the oath or declaration is objected to by the Examine 15 the oath or declaration is objected to by the Examine 15 the oath or declaration is objected to by the Examine 15 the oath or declaration is objected to by the Examine 15 the oath or declaration is objected to by the Examine 15 the oath or declaration is objected to by the Examine 15 the oath or declaration is objected to by the Examine 15 the oath or declaration is objected to by the Examine 15 the oath or declaration is objected to by the Examine 15 the oath or declaration is objected to by the Examine 15 the oath or declaration is objected to by the Examine 15 the oath or declaration is objected to by the Examine 15 the oath or declaration is objected to by the Examine 15 the oath or declaration is objected to by the Examine 15 the oath or declaration is objected to by the Examine 15 the oath or declaration is objected to be objected t | election requirement. T. Pepted or b) objected to by the following(s) be held in abeyance. See on is required if the drawing(s) is objected to by the left. | e 37 CFR 1.85(a). jected to. See 37 CFR | |
| Priority under 35 U.S.C. § 119 | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list of | s have been received. s have been received in Applicati ity documents have been receive (PCT Rule 17.2(a)). | on No ed in this National Sta | nge |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 07/06/2005 | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | ate | |

DETAILED ACTION

Acknowledgement of Preliminary Amendments

1. For the record, acknowledgement is made of the applicant's preliminary amendments to the claims under 37 CFR 1.115. It is acknowledged that applicant amended claims, 1-12, and submitted new claims, 13-17. Under examination are the new and amended claims, 1-17.

Acknowledgement for Invoking 35 USC § 112, Sixth Paragraph

2. For the record, the examiner acknowledges the applicant for invoking 35 USC § 112, Sixth Paragraph, which states:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

As such, the claim limitations are being treated under 35 U.S.C. 112, sixth paragraph. However, if a claim limitation does not use the phrase "means for" or "step for," the examiner will not treat such a claim limitation under 35 U.S.C. 112, sixth paragraph.

Claim Objections

- 3. Claim 14 recites the limitation "the cardiac system" in the end of claim. There is insufficient antecedent basis for this limitation in the claim.
- 4. Claim 15 recites the limitation "the respiratory system" in the end of claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

Application/Control Number: 10/541,624 Page 3

Art Unit: 3768

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Strommer'375 (US Patent No. 2002/0049375 A1).

Claim 1: Strommer'375 teaches a method of tracking an instrument that is inserted into the body of a patient (abstract). Strommer'375 also teaches the procedure of detecting an organ timing signal [movement signal] of the inspected organ, detecting a plurality of two-dimensional images of the inspected organ using an image detector, and detecting the location and orientation of the image detector (Page 3, Para 0033). Strommer'375 teaches displaying an image sequence of a moving inspected organ and each image in the image sequence is associated with the location and the orientation of the image within a predetermined coordinate system (Page 3, Para 0036). Strommer'375 further teaches selecting one of the previously stored two-dimensional images according to a real-time reading of the organ timing signal and displaying the selected two-dimensional image (Page 3, Para 0036). Strommer'375 teaches a method detecting a real time two-dimensional image of the inspected organ, detecting the location and orientation of the surgical tool (Page 4, Para 0043).

Claim 2/1: Strommer'375 teaches a method wherein an electrocardiogram detected the movement signal (Figure 12, Element 406). Strommer'375 also teaches using a respiratory rate monitor (Page 10, Para 0149).

Art Unit: 3768

Claim 3/1: Strommer'375 teaches a method wherein the position of the instrument is represented superimposed [superposed] on the selected 2D images (Page 4, Para 41).

Claim 4/1: Strommer'375 teaches 2D images from a single movement phase are available for selection from the image database (Page 18, Para 0245).

Claim 5/1: Strommer'375 teaches a method steps b & c - e are carried out a number of times (Page 7, 0110-0111) and in varying order (Figure 10 & Figure 22)

Claim 6/1: Strommer'375 teaches a method wherein the image database contains 2D images from various projection directions (Page 7, Para 0110-0111 & Page 8, Para 0119).

Claim 7/1: Strommer'375 teaches a method wherein the 2D images are generated by means of X-radiation and/or ultrasound (Figure 12, Element 404 & Page 7, Para 0101).

Claim 8/1: Strommer'375 teaches a method wherein a sensor [reference probe] is mounted on the image detector of the two-dimensional image acquisition system (Page 6, Para 0093). Strommer'375 further teaches that the image acquisition system consists of a two-dimensional image acquisition device (Page 7, 0100) wherein the two-dimensional image acquisition device can be of any type known in the art, such as an x-ray (Page 7, Para 0101).

Claim 9/1: Strommer'375 teaches a method wherein at least one sensor [reference probe] is arranged on or in the body of the patient (Page 6, Para 0093).

Art Unit: 3768

Claim 10/1: Strommer'375 teaches a method wherein the organ timing signal [breathing movement (Page 10, Para 0149)] is compensated for using pre-stored images [models] of the body (Page 3, Para 0032). Strommer'375 teaches that cyclic organs, such as an artery, constantly moves and that prior art were substantially inaccurate in representing information (Page 2, Para 0026).

Page 5

Claim 11: Strommer 375 teaches an arrangement for tracking an instrument that is inserted into the body of a patient (abstract). Strommer 375 teaches a device for generating 2D images of a body volume of interest (Figure 12, Element 418 & 404). Strommer 375 teaches a unit for determining set imaging parameters of the device (Figure 12, Element 408 & 402). Strommer 375 teaches a signal measurement unit for detecting a movement signal which represents movement phases of a periodic internal movement of the body (Figure 12, Element 406). Strommer 375 teaches a storage unit for storing an image database of 2D images of the body volume together with the associated imaging parameters and the associated movement phases (Figure 12, Element 414). Strommer 375 teaches a position measurement unit for determining the spatial position of the instrument that is inserted into the body (Figure 12, Element 408, 432_N, 432₁, & 432₂). Strommer 375 teaches a control and computation unit for selecting at least one 2D image from the image database, which 2D image corresponds in terms of its associated movement phase to the movement phase belonging to the spatial position of the instrument, and for determining the position of the instrument on the selected 2D image (Figure 12, Element 402).

Art Unit: 3768

Claim 12/11: Strommer'375 teaches an arrangement wherein it is designed for carrying out a method as claimed 1 (Figure 12).

Page 6

Claim 13: Strommer'375 teaches a real-time imaging system which constantly provides a real-time image of the body of the patient (Figure 16A, Element 484). Strommer'375 teaches the real-time imaging system is located outside of the patient either above or below and is a fluoroscopic or ultrasound system (Page 16, Para 0227). Strommer'375 teaches an instrument tracking system that is capable of generating and storing 2D images of a volume of interest in a body (Figure 12, Element 50) prior to insertion of an instrument into the body. It has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense, In re Hutchison 69 USPQ 138. Strommer 375 also teaches an instrument tracking system for detecting an organ timing signal [movement signal] of the inspected organ, detecting a plurality of two-dimensional images of the inspected organ using an image detector, and detecting the location and orientation of the image detector (Page 3, Para 0033). Strommer'375 teaches displaying an image sequence of a moving inspected organ and each image in the image sequence is associated with the location and the orientation of the image within a predetermined coordinate system (Page 3, Para 0036). Strommer'375 further teaches selecting one of the previously stored two-dimensional images according to a real-time reading of the organ timing signal and displaying the selected two-dimensional image (Page 3, Para 0036). Strommer 375 teaches a means for tracking the position of the instrument upon insertion into the body (Figure 12,

Art Unit: 3768

Element 408). Strommer'375 teaches a means for superimposing the position of the instrument with the selected, stored 2D image (Figure 12, Element 416).

Claim 14/13: Strommer'375 teaches an instrument tracking system wherein the periodic internal movement of the body is caused by the cardiac system (Page 6, Para 0094 & Page 10, Para 0149).

Claim 15/13: Strommer'375 teaches an instrument tracking system wherein the periodic internal movement of the body is caused by the respiratory system (Page 6, Para 0094 & Page 10, Para 0149).

Claim 16/13: Strommer'375 teaches an instrument tracking system wherein the means for measuring organ timing signal [movement phases] includes an electrocardiogram (Figure 12, Element 406 & Figure 18, Element 632).

Claim 17/13: Strommer'375 teaches an instrument tracking system comprising at least one reference probe positioned on at least one of the means for generating 2D images and the body (Page 6, Para 0093 & Figure 12, Element 420).

Conclusion

- 7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
 - a. Boese; Jan et al. Method and device for marking three-dimensional structures on two-dimensional projection images, 12/21/2006. US 2006/0285738 A1.
 - b. Hunter, Mark et al. Navigation system for cardiac therapies, 05/20/2004.

 US 20040097806 A1.

Application/Control Number: 10/541,624 Page 8

Art Unit: 3768

c. Mostafavi, Hassan. Method and system for predictive physiological gating, 09/15/2005. US 2005/0201510 A1.

- d. Okerlund, Darin R. et al. Method, system and computer product for cardiac interventional procedure planning, 10/02/2003. US 2003/0187358 A1.
- e. Shachar, Yehoshua. System and method for radar-assisted catheter guidance and control, 05/05/2005. US 2005/0096589 A1.
- f. Thomson, Euan. Apparatus and method for radiosurgery, 12/30/2004.
 US 20040267113 A1.
- g. Vass, Melissa et al. METHOD AND APPARATUS FOR MEDICAL INTERVENTION PROCEDURE PLANNING AND LOCATION AND NAVIGATION OF AN INTERVENTION TOOL, 04/14/2005. US 2005/0080328 A1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helene Bor whose telephone number is 571-272-2947. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3768

Page 9

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